UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

ALVOTECH USA INC. and
ALVOTECH HF.,

Plaintiffs,

v.

ABBVIE INC. and
ABBVIE BIOTECHNOLOGY LTD.,

Defendants.

Civil Action No. _____

JURY TRIAL DEMANDED

PLAINTIFFS ALVOTECH USA INC. AND ALVOTECH HF.'S DECLARATORY JUDGMENT COMPLAINT FOR PATENT NON-INFRINGEMENT, INVALIDITY, AND UNENFORCEABILITY

Plaintiffs Alvotech USA Inc. ("Alvotech USA") and Alvotech hf. (collectively, "Alvotech") for their declaratory judgment complaint against Defendants AbbVie Inc. and AbbVie Biotechnology Ltd. (collectively, "AbbVie"), by their undersigned attorneys, hereby state and allege as follows:

NATURE OF THE CASE

1. This case aims to bring to a just end Defendants' ongoing monopoly on the life-changing drug adalimumab. Through the acquisition and threatened enforcement of an outrageous number of patents of dubious validity—in excess of 100—defendants have, to date, avoided any competition on adalimumab, which they sell as Humira®. Any competitor that desires to bring a biosimilar version of Humira® to market is threatened with crushing, ruinous litigation on these patents. This abuse of the patent acquisition and litigation process has resulted in AbbVie alone selling adalimumab in the United States, despite the patents on the molecule expiring in 2016. It is time for this monopoly to end.

2. AbbVie sells Humira® as a liquid, injectable formulation of the monoclonal antibody adalimumab. The FDA has approved Humira® to treat certain autoimmune diseases, including rheumatoid arthritis, that are triggered by high levels of tumor necrosis factor alpha ("TNFα"). AbbVie first began selling Humira® in the United States in 2003, in a different formulation and concentration (50 mg/ml) than its current product (100 mg/ml). According to AbbVie's advertisements, the 100 mg/ml formulation causes patients less pain.

3. AbbVie had tested the less painful 100 mg/ml formulation by 2010 and the FDA approved it in 2015. Notwithstanding that formulation's touted benefits, AbbVie waited nearly three years after FDA approval to bring it to market. During that time, several companies developed 50 mg/ml biosimilar formulations because the 50 mg/ml formulation was the only version on the market. On information and belief, AbbVie waited to launch the 100 mg/ml product until those programs were well underway, in an effort to render obsolete these early competitors' development efforts. AbbVie thus withheld from the market its purportedly less painful formulation until it was strategically and financially favorable to do so in order to extend its monopoly.

4. To date, there is no biosimilar version of either formulation of Humira® on the U.S. market, though many 50 mg/ml formulations are available in Europe. Over the last five years, Plaintiffs independently developed a biosimilar of the 100 mg/ml version of Humira®, known as AVT02. If approved by the FDA, AVT02 will be the only biosimilar of the 100 mg/ml version of Humira® approved in the United States. AVT02 will be priced lower than Humira®, and thus has the potential to save American consumers and payors billions of dollars annually.

5. In theory, American consumers should have already been realizing these savings for years, from other biosimilar versions of Humira®. This is because the original patents on

adalimumab and methods of using it to treat TNFα disorders expired in 2016. AbbVie did not invent these original patents or adalimumab. Rather, in around 1995, a German company, BASF AG, filed a patent application disclosing adalimumab and methods of using it to treat TNFα-related autoimmune diseases. In 2001, after BASF had undertaken years of further development work, AbbVie's predecessor, Abbott Laboratories, purchased the rights to the drug, the patents, and all of BASF's additional work for $6.9 billion.

6. This purchase price turned out to be a bargain for AbbVie. Between 2003 and 2016, when BASF AG's original patents expired, AbbVie reportedly sold nearly $100 billion worth of Humira® worldwide. To put this in perspective, a drug with annual sales of $1 billion is considered a blockbuster in the pharmaceutical industry.

7. But this apparently was not enough for AbbVie. Despite having played no role in inventing adalimumab and having enjoyed a lengthy and profitable monopoly supported by BASF AG's original patents, AbbVie has nonetheless sought and obtained over 100 additional patents of dubious validity related to adalimumab that have lawlessly extended AbbVie's monopoly. AbbVie has received an enormous financial windfall from this misconduct—in just the last four years, since its monopoly should have run its course, AbbVie has reported selling over $75 billion worth of Humira®, and is forecasted to make an additional nearly $40 billion through 2022.

8. The Chief Executive Officer of AbbVie has referred to this excessive number of patents as a "minefield of IP." The goal of AbbVie's "minefield" on Humira® is not to protect innovation. Any innovations underlying Humira® were accomplished by BASF, as well as other companies working in the fields of TNFα inhibitors and antibody formulation that pre-dated AbbVie. Instead, as the name suggests, the goal of AbbVie's "minefield" is to deter competition

with Humira® through sheer numbers, which makes challenging the "minefield" in litigation cost and resource-prohibitive.

9. AbbVie is currently utilizing its "minefield" against Alvotech. As detailed below, AbbVie has asserted that AVT02 will infringe 62 of AbbVie's patents, and has refused to limit itself to any reasonable subset of these patents to determine whether market entry of AVT02 should be permitted. Given AbbVie's refusal, Alvotech identified the four patents-in-suit as appropriate to litigate because invalidation of these four patents should pave the way for market entry of AVT02: U.S. Patent Nos. 8,420,081; 9,085,619; 8,926,975; and 8,961,973.

10. Like the original adalimumab patent, AbbVie did not invent anything claimed in each of the four patents-in-suit. The '081 and '619 patents relate to the self-buffering formulation used by AbbVie for the 100 mg/ml concentration of Humira®. Such formulations were invented by Amgen before AbbVie, as Plaintiffs will prove.

11. The '975 and '973 patents relate to methods of treating ankylosing spondylitis (a form of arthritis) and Crohn's disease using adalimumab, respectively. Both of these diseases are autoimmune disorders triggered by high levels of TNFα. AbbVie did not invent the use of adalimumab for the treatment of these diseases. Indeed, BASF AG disclosed the use of adalimumab to treat TNFα-related autoimmune diseases in its original patent as far back as 1996.

12. A similar story is true for the remainder of AbbVie's IP "minefield." Dozens of these patents, for example, cover manufacturing processes. AbbVie did not invent novel, non-obvious manufacturing processes related to Humira®. Instead, AbbVie has patented old processes of manufacture routinely applied to antibodies like adalimumab.

13. Even though AbbVie invented none of these things, it patented them all, resulting in the "minefield" that, thus far, has succeeded in keeping lower-cost biosimilars off the market.

Every company that has even hinted at challenging AbbVie's portfolio in court has been threatened with at least 60 patents from AbbVie's "minefield," and each has settled without the merits of any single patent being addressed in court, with AbbVie securing years of additional time for its monopoly. AbbVie has thus managed to subvert the very process designed to prevent its wrongdoing "by means of the overpowering threat of disastrous litigation." *See Automatic Radio Mfg. v. Hazeltine Research*, 339 U.S. 827, 834 (1950).

14. In addition to using its patent minefield to run up litigation costs, AbbVie has filed two improper suits against Alvotech hf. over the last two months in the Northern District of Illinois to further its strategy of delay and running up legal expenses for potential competitors. In the first, AbbVie falsely alleges that Alvotech hf. stole the AVT02 manufacturing process in 2018 by hiring a former AbbVie employee. But Alvotech hf. began developing its manufacturing process in 2013 and had started its at-scale 2000 L batches of AVT02 produced in Iceland before that employee even began at Alvotech. In the second, AbbVie alleges patent infringement based on the patent dance of the BPCIA. But AbbVie knows that *Alvotech USA* is the BLA applicant for AVT02 and therefore is a necessary party to any infringement suit. AbbVie also knows that Alvotech USA is only subject to personal jurisdiction, and venue is only proper, in this district. Rather than sue a necessary party in the proper venue, AbbVie filed its improper suit against Alvotech hf. alone in Illinois to further increase expense and delay resolution on the merits.

15. This Court is the proper venue to timely resolve the patent dispute between Alvotech and AbbVie. AbbVie sells approximately $40 million worth of Humira® in the U.S. every day. Even a one-month delay in resolution on the merits rewards AbbVie with over $1 billion in revenue. If AbbVie had followed the rules, it would have filed suit here and Alvotech

would not be forced to file this declaratory judgment action. AbbVie ignored the rules because doing so benefits its bottom line.

16. Plaintiffs thus bring this action to challenge AbbVie's improper patents on adalimumab that have extended AbbVie's market monopoly on adalimumab far beyond the time to which AbbVie was legitimately entitled. The time for lower-cost competition to Humira® has come.

THE PARTIES

17. Alvotech USA Inc. is a corporation organized and existing under the laws of Commonwealth of Virginia, with its corporate headquarters at 1201 Wilson Blvd., Ste. 2130, Arlington, Virginia 22209.

18. Alvotech hf. is a corporation organized and existing under the laws of the Republic of Iceland, with its corporate headquarters at Saemundargata 15-19, 101 Reykjavik, Iceland. Alvotech USA is a wholly-owned subsidiary of Alvotech hf.

19. The Alvotech family of companies is becoming a global leader in the biosimilar space, seeking to deliver high-quality, cost-competitive products and services to patients and its partners worldwide. The Alvotech family is striving to make biologic drugs more accessible to those who might not otherwise be able to afford them.

20. Different parts of the Alvotech family play different roles in the overall organization. For example, in Reykjavik, Iceland, Alvotech hf. houses a state-of-the-art, multi-product, 140,000 square foot biopharmaceutical facility, with personnel specializing in process and product development and commercial manufacturing and with extensive analytical expertise.

21. For its part, employees of Alvotech USA are responsible for the Alvotech family's legal, governmental policy, and regulatory affairs. This Virginia-based company employs, among

others, the Alvotech family's head of regulatory affairs, its chief intellectual property counsel, and its chief scientific officer.

22. Consistent with its corporate function and mission, Alvotech USA Inc. is the applicant for FDA biologics license application ("BLA") No. 761205 under 42 U.S.C. § 262(k) (hereafter, "subsection (k)") for a 100 mg/ml adalimumab biological product that is highly similar to AbbVie's 100 mg/ml Humira® product (hereafter, "AVT02"). Alvotech hf. is named in Alvotech USA's BLA as the drug substance and drug product manufacturer.

23. On information and belief, AbbVie Inc. is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie Inc. is the holder of BLA No. 125057 for Humira®.

24. On information and belief, AbbVie Biotechnology Ltd. is a corporation organized and existing under the laws of Bermuda, with a place of business at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda. On information and belief, through intermediate organizations, AbbVie Inc. owns AbbVie Biotechnology Ltd.

25. AbbVie Inc. markets Humira® in the United States, and has done so continuously since at least the beginning of 2003. According to AbbVie Inc., the patents-in-suit relate to Humira®. On information and belief, AbbVie Inc. and AbbVie Biotechnology Ltd. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the patents-in-suit.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

26. This is a declaratory judgment suit arising under the patent laws of the United States, Title 35, United States Code. This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A substantial

controversy exists between Plaintiffs and AbbVie, in which the parties have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment from this Court.

27. In amending the Public Health Service Act, the Patent Act, and the Declaratory Judgment Act, and through the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), Congress created a new pathway for FDA review and approval of "biosimilar" biological products, as well as new mechanisms to resolve patent disputes that may arise with respect to such biological products.

28. By creating an abbreviated and more cost-effective path to biosimilar approval, Congress designed the BPCIA to ensure that lower-cost alternatives to expensive reference products enter the U.S. market.

29. On September 4, 2020, Alvotech USA applied for licensure of AVT02 with the FDA. On November 3, 2020, the FDA notified Alvotech USA that Alvotech USA's application was sufficiently complete to permit substantive review by the FDA. The FDA assigned number 761205 to Alvotech USA's AVT02 BLA.

30. On November 5, 2020, Alvotech USA provided AbbVie Inc. with the AVT02 BLA application and voluminous other information required under 42 U.S.C. § 262(*l*)(2)(A), initiating a series of statutorily-required disclosures (colloquially known as the "patent dance") between Alvotech USA and AbbVie Inc. Alvotech USA produced 118,846 pages of documents and provided its productions in three formats: in the format provided to the FDA, in PDF format, and in a format that could be loaded onto document review software. In addition to its AVT02 BLA, Alvotech USA's production included hundreds of additional manufacturing documents, totaling over 25,000 pages, including batch and laboratory records.

31. On January 4, 2021, under 42 U.S.C. § 262(*l*)(3)(A), AbbVie Inc. identified 63 patents (AbbVie's "3(A) List"), including the patents-in-suit, which it alleged could reasonably be asserted against Alvotech USA if Alvotech USA were to manufacture, use, offer for sale, sell in the United States, or import into the United States AVT02 without a license from AbbVie. Despite AVT02 being a 100 mg/ml formulation of adalimumab, AbbVie Inc. included in its 3(A) List one entire patent and several other patents with claims directed to 50 mg/ml formulations that could not reasonably be asserted against AVT02.

32. On January 14, 2021, under 42 U.S.C. § 262(*l*)(3)(B), Alvotech USA provided AbbVie Inc. detailed statements that describe, on a claim by claim basis for each of the 63 patents, the factual and legal basis why each claim of the 63 asserted patents is invalid, unenforceable, and/or will not be infringed by the commercial marketing of AVT02 (Alvotech USA's "3(B) Statement"). Alvotech USA's detailed 3(B) Statement included over 6,000 pages of explanation and claim charts, with citations to Alvotech USA's AVT02 BLA and manufacturing documents. Alvotech USA also cited and produced over 270 pieces of prior art, demonstrating that AbbVie's patents are invalid as anticipated and/or obvious.

33. On March 15, 2021, AbbVie Inc. provided to Alvotech USA a statement of infringement and validity under 42 U.S.C. § 262(*l*)(3)(C) on 62 of their 63 listed patents. In this statement, AbbVie Inc. failed to satisfy its statutory obligation under § 262(*l*)(3)(C) to respond to Alvotech USA's statement concerning validity and enforceability. As a non-limiting example, AbbVie Inc. chose to provide no response on invalidity allegations regarding claims for which AbbVie Inc. had decided not to provide infringement contentions. In addition, AbbVie Inc. failed to provide a good faith response to a number of Alvotech USA's invalidity allegations, citing only boilerplate legal tests without providing any explanation.

34. Notwithstanding AbbVie Inc.'s deficiencies, starting no later than March 17, 2021, Alvotech USA engaged in good faith negotiations under 42 U.S.C. § 262(*l*)(4)(A) to identify the patents on the 3(A) List that should be the subject of "the immediate patent infringement action" authorized under 42 U.S.C. § 262(*l*)(6). AbbVie did not engage in good faith negotiations.

35. After first proposing a mutual exchange, which AbbVie Inc. rejected, Alvotech USA provided AbbVie Inc. with a list of the four patents-in-suit. Alvotech USA reasonably anticipated that AbbVie Inc. would respond with its own list of patents that should be litigated, and then the parties would continue to negotiate. Instead, on March 29, 2021, the last day possible under the statute, AbbVie Inc. provided no substantive response to Alvotech USA's proposal, instead taking the position that Alvotech USA was somehow required to choose all 62 of AbbVie's remaining patents if it wanted to bring its product to market and that "litigating only those four patents alone will not in any way 'resolve' the issues of patent infringement with respect to Alvotech's product." Notwithstanding AbbVie's failure to substantively engage, Alvotech satisfied its obligations under § 262(*l*)(4).

36. AbbVie Inc. thus refused to limit its asserted patents in any meaningful way during the BPCIA patent dance, contrary to the underlying purpose of the statute. Consistent with its long-held strategy of attempting to bury its competitors, AbbVie Inc. thus raised the specter of ruinous litigation if Alvotech USA sought to bring its biosimilar product to market, exactly as the Supreme Court proscribes, in order to force Alvotech to settle on AbbVie's terms. Notably, in correspondence between the parties, AbbVie Inc. stated it was unwilling to license even a single one of the 63 patents it had originally asserted in the patent dance.

37. As of March 29, 2021, AbbVie Inc. had 30 days to bring an action for patent infringement against Alvotech USA with respect to the four patents-in-suit. *See* 42 U.S.C.

§ 262(*l*)(6). Under 35 U.S.C. § 271(e), the filing of Alvotech USA's BLA is an artificial act of infringement by the BLA filer (or "subsection (k) applicant"), here Alvotech USA, for each of the patents-in-suit.

38. On April 27, 2021, AbbVie Inc. and AbbVie Biotechnology Ltd. sued Plaintiff Alvotech hf., but not Alvotech USA, for infringement of the patents-in-suit in the United States District Court for the Northern District of Illinois.

39. AbbVie's suit is improper under the BPCIA, the Patent Act, and the Federal Rules of Civil Procedure. AbbVie's suit fails to include the actual applicant for licensure of AVT02, Alvotech USA. Because it is the BLA applicant at issue, Alvotech USA is the required defendant under the BPCIA and has committed the statutorily required act of infringement that creates jurisdiction under the patent statute. *See, e.g.*, 42 U.S.C. § 262(*l*)(6); 35 U.S.C. § 271(e)(2)(C)(i). On information and belief, AbbVie declined to sue Alvotech USA because AbbVie does not want to litigate this dispute in the Eastern District of Virginia, which is well-known for potentially resolving patent disputes faster than other jurisdictions. Alvotech USA is not subject to personal jurisdiction in the Northern District of Illinois and thus cannot be sued there.

40. AbbVie's misconduct has necessitated this declaratory judgment suit, which normally Plaintiffs would have filed as a counterclaim to AbbVie's affirmative claim of patent infringement, had AbbVie brought its claims against the proper parties and in the proper jurisdiction.

41. As part of its remedial steps to cure AbbVie's violation of the BPCIA, the Patent Act, and the Federal Rules of Civil Procedure, Alvotech USA has undertaken the additional required actions under the BPCIA that permit this declaratory judgment suit. On May 3, 2021, Alvotech USA provided the Secretary of Health and Human Services with notice and a copy of

AbbVie's complaint in compliance with 42 U.S.C. § 262(*l*)(6)(C)(i). On May 11, 2021, AbbVie Inc. received Notice of Commercial Marketing from Alvotech USA pursuant to 42 U.S.C. § 262(*l*)(8)(A). *See* 42 U.S.C. § 262(*l*)(9).

Personal Jurisdiction – AbbVie Inc.

42. This Court has personal jurisdiction over AbbVie Inc. because AbbVie Inc. has purposefully directed at the Commonwealth of Virginia numerous activities giving rise to this action including (a) conducting the patent dance under 42 U.S.C. § 262(*l*) with Virginia-based Alvotech USA; (b) engaging in inequitable conduct and/or having unclean hands in connection with the prosecution of patents protecting Humira® (including those asserted against Alvotech USA) before the Virginia-based U.S. Patent and Trademark Office; and (c) because AbbVie Inc. reasonably expected to litigate a biosimilar case involving AVT02 and Humira® in Virginia, the domicile of subsection (k) applicant Alvotech USA. Assertion of jurisdiction is both reasonable and fair.

43. As described above, Alvotech USA is the subsection (k) applicant triggering the statutory artificial act of infringement under 35 U.S.C. § 271(e)(2)(C).

44. Alvotech USA initiated the patent dance with AbbVie Inc. AbbVie Inc. knows that Alvotech USA is the subsection (k) applicant and that Alvotech USA is domiciled in Virginia, at least because Alvotech USA's principal place of business is listed on the cover letter for its subsection (k) application and Alvotech USA sent the BLA and other information required by 42 U.S.C. § 262(*l*)(2) from its headquarters in Arlington, Virginia. Further, Alvotech USA's principal place of business in Virginia is a matter of public record and has been prominently displayed on Alvotech's website since before the patent dance here began.

45. After Alvotech USA sent its subsection (k) application to AbbVie Inc., AbbVie Inc. directed its enforcement activities related to its patents protecting Humira® at Alvotech USA, a resident of Virginia.

46. AbbVie Inc.'s enforcement activities against Alvotech USA include at least the following actions:

a. Sending the 3(A) List that AbbVie Inc. purported could reasonably be asserted against Alvotech USA. (**Exhibit 1.**)

b. Failing to identify any patent it would be willing to license to Alvotech USA that would obviate the need for patent litigation. (*Id.*)

c. Sending more than 2000 pages of contentions arguing that Alvotech USA's subsection (k) application infringed valid, enforceable claims of AbbVie Inc.'s patents.

d. Expressly authorizing Alvotech USA to have access to AbbVie Inc.'s confidential documents alleging infringement of alleged valid and enforceable claims of AbbVie Inc.'s patents.

e. Sending at least two additional communications to counsel for Alvotech USA as part of the patent dance negotiations under § 262(*l*)(4), reflecting AbbVie Inc.'s continuing intent to assert the patents-in-suit against Alvotech USA, knowing that AbbVie Inc. would have to bring suit on those patents against Alvotech USA.

47. In addition to and as part of, its enforcement strategy related to the patent dance, AbbVie Inc. engaged in patent misuse and has unclean hands by engaging in a pattern of misconduct designed to shield its patents from meaningful litigation, thus reducing the risk that

those patents would undergo the legal scrutiny necessary to ensure that AbbVie Inc.'s monopolies are kept within their legitimate scope. As detailed further below, AbbVie Inc.'s behavior is directed at eliminating legitimate competition from biosimilar companies, including Virginia-based Alvotech USA. AbbVie Inc.'s behavior giving rise to patent misuse and unclean hands also includes engaging in inequitable conduct, as described in the appropriate counts below, which conduct took place at the U.S. Patent and Trademark Office in Alexandria, Virginia.

48. AbbVie Inc. reasonably expected to be haled into court in Virginia.

49. First, AbbVie engaged in the above-discussed process knowing that this district is the only district with personal jurisdiction over Alvotech USA and for which venue is proper.

50. Alvotech USA, as the subsection (k) applicant, is the only entity that can trigger the alleged artificial act of infringement permitting AbbVie to assert its patent portfolio. For that reason, Alvotech USA is a proper defendant and is a necessary party to any patent infringement litigation brought under 42 U.S.C. § 262(*l*) and 35 U.S.C. § 271(e)(2).

51. Alvotech USA is only subject to personal jurisdiction in Virginia. AbbVie Inc. therefore can only bring suit to enforce its adalimumab patents against Alvotech USA in Virginia.

52. As part of its enforcement strategy, AbbVie Inc. has attempted to disadvantage Alvotech USA by filing suit against Alvotech hf. in the Northern District of Illinois, and not suing Alvotech USA, the subsection (k) applicant.

53. On information and belief, AbbVie Inc. filed suit asserting the patents-in-suit in the Northern District of Illinois for the improper purpose of extending its monopoly over adalimumab by delaying resolution of the patent issues.

54. On information and belief, AbbVie Inc. filed that suit in an improper forum, despite knowing that Congress has enacted a statutory framework allowing for biosimilar competition and

setting forth patent dispute resolution procedures that may result in a reference product sponsor like AbbVie Inc. bringing suit against a subsection (k) applicant like Alvotech USA. By selling a reference product and asserting patents allegedly directed to that product, AbbVie Inc. must expect to sue a subsection (k) applicant and/or be sued by a subsection (k) applicant in a forum where the subsection (k) applicant is subject to personal jurisdiction and where venue over the subsection (k) applicant is proper. A complaint seeking a declaratory judgment of non-infringement, such as in this case, is an inverted infringement action, and Alvotech USA is the proper defendant against which AbbVie Inc. could only properly bring suit in the Eastern District of Virginia.

55. Second, on information and belief, either directly or through its subsidiaries, agents, and/or affiliates, AbbVie Inc. regularly and continuously transacts business generally within the Commonwealth of Virginia and specifically within this district, including by selling, offering for sale, marketing, distributing, and/or importing more than 30 pharmaceutical products, including Humira®. AbbVie Inc. has purposefully availed itself of the privilege of conducting business in this forum by commercializing, advertising, and marketing its pharmaceutical products in the Commonwealth of Virginia and this judicial district, and AbbVie Inc. derives substantial revenue from the sale of those products throughout Virginia.

56. Third, AbbVie Inc. has also availed itself of the legal protections of the Commonwealth of Virginia by having filed at least one declaratory judgment suit regarding patent infringement in this district. *See, e.g.*, *AbbVie Inc. et al. v. Medimmune Ltd.*, Civil Action No. 2:16-cv-00322-AWA-DEM, D.I. 1 (E.D. Va. Jun. 22, 2016).

57. Fourth, AbbVie Inc. has registered with the Virginia's State Corporation Commission and appointed Corporate Creations Network Inc., a business entity that is authorized to transact business in Virginia, as its agent to accept service in Virginia.

58. Assertion of personal jurisdiction over AbbVie Inc. in Virginia is reasonable and fair.

Personal Jurisdiction – AbbVie Biotechnology Ltd.

59. This Court has personal jurisdiction over AbbVie Biotechnology Ltd. because AbbVie Biotechnology Ltd. has purposefully directed numerous activities to the Commonwealth of Virginia, the claims herein arise out of those activities, and the assertion of jurisdiction is both reasonable and fair.

60. First, on information and belief, AbbVie Biotechnology Ltd. has allowed AbbVie Inc. to threaten Alvotech USA, a resident of this district, with certain pre-suit, enforcement activities relating to the patents-in-suit and Alvotech USA's BLA application, described above. AbbVie Biotechnology Ltd. and AbbVie Inc. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the patents-in-suit in order to protect the Humira® monopoly discussed above. On information and belief, AbbVie Biotechnology Ltd. allowed AbbVie Inc. to engage in these enforcement activities against Alvotech USA, the subsection (k) applicant, knowing that Alvotech USA was a resident of this district and could only be haled into court in this district.

61. Second, AbbVie Biotechnology Ltd. has directed at the Patent Office, which is located in Alexandria, Virginia, various patent prosecution activities giving rise to Plaintiffs' claims of unenforceability due to inequitable conduct, unclean hands, and patent misuse. For example, during the prosecution of the patent family of at least one of the patents-in-suit (*e.g.*, U.S. Patent No. 8,961,973), AbbVie Biotechnology Ltd. made misrepresentations and omissions to the Patent Office that were material to patentability and, on information and belief, did so with the specific intent to mislead or deceive the Patent Office and with knowledge that the misrepresentations were material to patentability.

62. AbbVie Biotechnology Ltd. is also a wholly-owned subsidiary of AbbVie Inc. and on information and belief, manufactures pharmaceutical products, like Humira®, for distribution, sale, and use in Virginia, including in this district. AbbVie Biotechnology Ltd. has also obtained and maintained certain of the patents-in-suit before the Patent Office.

63. Further, to the extent AbbVie Biotechnology Ltd. has not filed in the Patent Office a written designation stating the name and address of a person residing within the United States on whom may be served process or notice of proceedings affecting the patents or rights thereunder, this Court has personal jurisdiction over AbbVie Biotechnology Ltd. pursuant to 35 U.S.C. § 293.

64. Alternatively, this Court may exercise personal jurisdiction over AbbVie Biotechnology Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Alvotech's claims arise under federal law; (b) AbbVie Biotechnology Ltd. is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) AbbVie Biotechnology Ltd. has sufficient contacts with the United States as a whole such that this Court's exercise of personal jurisdiction over AbbVie Biotechnology Ltd. satisfies due process.

65. AbbVie Biotechnology Ltd. has sufficient contacts with the United States as a whole based on its activities to obtain and maintain certain of the patents-in-suit before the Patent Office, as well as its previous enforcement activities in United States District Courts. On information and belief, AbbVie Biotechnology Ltd. is the assignee for at least ninety-eight issued U.S. patents. On information and belief, AbbVie Biotechnology Ltd. through its consultants and/or attorneys affirmatively participated in the prosecution of these patents, including substantial communications with the Patent Office located within Alexandria, Virginia. Further, AbbVie Biotechnology Ltd. has enforced its patents in United States District Courts in at least three separate actions. *See AbbVie Inc. et al. v. Boehringer Ingelheim Int'l GMBH*, No. 1:17-cv-01065-

MSG-RL (D. Del. Aug. 2, 2017) (ECF No. 1) (suit properly brought where U.S.-based defendants incorporated); *AbbVie Inc. et al. v. Sandoz, Inc.*, No. 3:18-cv-12668-FLW-LHG (D.N.J. Aug. 10, 2018) (ECF No. 1) (suit properly brought where U.S.-based defendant had principal place of business); *AbbVie Inc. et al. v. Amgen Inc.*, No. 1:16-cv-00666-MSG (D. Del. Aug. 4, 2016) (ECF No. 1) (suit properly brought where defendant incorporated). AbbVie Biotechnology Ltd. has also filed suit against the Commissioner of the Patent Office within this district to obtain a longer patent life span for a patent relating to a formulation of Humira®. *See AbbVie Biotechnology Ltd. v. Lee*, No. 1:12-cv-01511-AJT-TRJ (E.D. Va. Dec. 28, 2012) (ECF No. 1).

Venue

66. Venue is proper in this district under 28 U.S.C. § 1391 because AbbVie Inc. and AbbVie Biotechnology Ltd. are subject to personal jurisdiction in this district.

67. Venue is also proper because a substantial part of the events giving rise to AbbVie Inc.'s assertions that Alvotech USA has or will infringe the patents-in-suit occurred in this district. Alvotech USA, a resident of this district, prepared and filed its subsection (k) application for its biosimilar product from within this district. Alvotech USA also has conducted substantial activities, including correspondence with the FDA and AbbVie Inc., in furtherance of its subsection (k) application from within this district. Alvotech USA also served AbbVie Inc.'s registered agent in Virginia (Corporate Creation Network Inc.) with correspondence and documents related to Alvotech USA's subsection (k) application. Further, AbbVie Inc. directed pre-suit patent communications to Alvotech USA, a resident of this district, asserting and maintaining AbbVie Inc.'s position that Alvotech USA would infringe the patents-in-suit if it were to manufacture, use, offer for sale, sell in the United States, or import into the United States its biosimilar product.

68. Alvotech USA has also performed substantial activities in this district relating to the development and future commercial marketing of its biosimilar product, through its regulatory affairs, government policy, and legal centers based in this district.

69. Further, venue is also proper because a substantial part of the events giving rise to Plaintiffs' assertions that AbbVie engaged in inequitable conduct before the Patent Office occurred in this district.

ACTS GIVING RISE TO THIS ACTION

Alvotech's AVT02 – the First Biosimilar to 100 mg/ml Humira®

70. The active ingredient in Alvotech's AVT02 product is adalimumab. Adalimumab belongs to a category of drugs known as biologics. It is a protein manufactured in living cells rather than by chemical synthesis. Adalimumab is a fully human, high-affinity, and neutralizing therapeutic antibody to human TNFα, a protein made by the human body as part of the body's immune response. Many diseases are known to be caused by high levels of TNFα and are treated with anti-TNFα biologics.

71. AbbVie's Humira® is an injectable formulation of adalimumab. The FDA first approved Humira® in 2002 as a treatment for rheumatoid arthritis, a chronic inflammatory disorder that affects the lining of the joints and is caused by high levels of TNFα. Patients with rheumatoid arthritis can suffer from painful swelling that might eventually result in bone erosion and joint deformity, as well as damage to other parts of the body. Humira® is now FDA-approved for other similarly painful and/or disruptive chronic disorders, all of which, like rheumatoid arthritis, are known to be TNFα-related disorders.

72. As first launched by AbbVie's predecessor Abbott in 2003, Humira® was a 50 mg/ml formulation that contained, among other things, a phosphate-citrate buffer. In 2018, facing potential competition for the first time, AbbVie began marketing a 100 mg/ml "citrate-free" (as

AbbVie calls it) formulation of Humira® in the U.S. In this "citrate-free" formulation, AbbVie eliminated the buffer from the 50 mg/ml formulation. AbbVie's advertising materials tout that the 100 mg/ml "citrate-free" formulation causes less pain than the 50 mg/ml formulation.

73. Plaintiffs Alvotech USA and Alvotech hf. have developed a biosimilar to the 100 mg/ml formulation of Humira®, known as AVT02. On information and belief, if the FDA approves AVT02, it will be the first biosimilar to the citrate-free, 100 mg/ml formulation of Humira® approved in the United States. Alvotech is committed to bringing its 100 mg/ml, bufferless formulation to market upon FDA approval in order to make the lower-cost alternative available to patients as quickly as possible.

74. The Alvotech family of companies developed AVT02 through years of rigorous testing and development efforts, starting in 2013. After selecting adalimumab for development, the Alvotech companies and their contractors generated expression vectors, genetically modified CHO cells to produce adalimumab, and analyzed thousands of the resulting CHO cell minipools for expression of adalimumab before selecting a unique AVT02 CHO cell clone for adalimumab production. Over the course of several years, scientists at multiple sites in Iceland and Europe developed upstream and downstream manufacturing processes to maximize production output and obtain high quality product. These scientists tested and adjusted parameters and steps, including medium and feeds, feed timing, temperature, culturing time, chromatography resins, loading density and wash steps, and more. The scientists completed the first at-scale GMP drug substance batch of AVT02 by early 2018.

75. In addition, Alvotech's scientists made and tested multiple formulations before settling on the AVT02 formulation. Alvotech's formulation uses different excipients than AbbVie's "citrate-free" formulation.

76. After developing its 100 mg/ml formulation of adalimumab, Alvotech sponsored multiple multicenter, double-blind clinical trials to compare the efficacy, immunogenicity, safety, pharmacokinetics, and tolerability of AVT02 to Humira® in patients. To date, hundreds of patients have enrolled in Alvotech's clinical trials of AVT02. Alvotech's clinical trials established that there is no clinically meaningful difference between AVT02 and Humira® in the safety, tolerability, and immunogenicity outcome measures. Alvotech's Phase III comparative clinical trial for AVT02 met its primary objective by demonstrating equivalent efficacy to Humira® in the measured parameters. Alvotech's clinical switching study (AVT02-GL-302) is ongoing.

77. Upon conclusion of the initial clinical trials, Alvotech prepared the voluminous documentation required by the FDA for a BLA for AVT02. As indicated above, after Alvotech USA filed its application on September 4, 2020, the FDA accepted Alvotech USA's AVT02 BLA on November 3, 2020.

THE PATENTS-IN-SUIT

U.S. Patent No. 8,420,081

78. U.S. Patent No. 8,420,081 ("the '081 patent"), titled "Antibody Formulations and Methods of Making Same," issued on April 16, 2013. A true and correct copy of the '081 patent is attached as **Exhibit 2**. On information and belief, the '081 patent is assigned to AbbVie Biotechnology Ltd. On information and belief, AbbVie Inc. and AbbVie Biotechnology Ltd. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '081 patent.

U.S. Patent No. 9,085,619

79. U.S. Patent No. 9,085,619 ("the '619 patent"), titled "Anti-TNF Antibody Formulations," issued on July 21, 2015. A true and correct copy of the '619 patent is attached as **Exhibit 3**. On information and belief, the '619 patent is assigned to AbbVie Biotechnology Ltd.

On information and belief, AbbVie Inc. and AbbVie Biotechnology Ltd. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '619 patent.

U.S. Patent No. 8,926,975

80. U.S. Patent No. 8,926,975 ("the '975 patent"), titled "Method of Treating Ankylosing Spondylitis," issued on January 6, 2015. A true and correct copy of the '975 patent is attached as **Exhibit 4**. On information and belief, the '975 patent is assigned to AbbVie Biotechnology Ltd. On information and belief, AbbVie Inc. and AbbVie Biotechnology Ltd. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '975 patent.

U.S. Patent No. 8,961,973

81. U.S. Patent No. 8,961,973 ("the '973 patent"), titled "Multiple-Variable Dose Regimen for Treating TNFα-Related Disorders," issued on February 24, 2015. A true and correct copy of the '973 patent is attached as **Exhibit 5**. On information and belief, the '973 patent is assigned to AbbVie Biotechnology Ltd. On information and belief, AbbVie Inc. and AbbVie Biotechnology Ltd. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '973 patent.

COUNT I

(Declaratory Judgment of Non-infringement of U.S. Patent No. 8,420,081)

82. Plaintiffs re-allege the foregoing paragraphs as if fully set forth herein.

83. Plaintiffs have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '081 patent under 35 U.S.C. § 271. On January 14, 2021, Alvotech USA provided AbbVie Inc. with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing, on a claim by claim basis, the factual and legal

bases for Alvotech USA's opinion that Plaintiffs will not infringe the '081 patent. Alvotech USA's detailed statement is within AbbVie's possession and is incorporated by reference herein. In addition, Plaintiffs cannot be liable for any infringement of the '081 patent because it is invalid and unenforceable.

84. On March 15, 2021, and pursuant to 42 U.S.C. § 262(*l*)(3)(C), AbbVie Inc. purported to provide Alvotech USA with its factual and legal bases for AbbVie Inc.'s opinion that Plaintiffs will infringe the '081 patent. AbbVie filed a suit for infringement of the '081 patent against Alvotech hf. on April 27, 2021 in the Northern District of Illinois, but Alvotech USA, a necessary party, is not subject to personal jurisdiction in that district and venue is improper there under 28 U.S.C. §§ 1400(b) and 1391.

85. As a result of AbbVie's allegations against Plaintiffs, an actual and justiciable controversy exists between Plaintiffs and AbbVie at least as to the infringement of the '081 patent.

86. Plaintiffs are entitled to a judicial declaration that the making, use, offer for sale, sale, or importation into the United States of Plaintiffs' biosimilar product does not and will not infringe any valid and enforceable claim of the '081 patent under 35 U.S.C. § 271. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT II

(Declaratory Judgment of Invalidity of U.S. Patent No. 8,420,081)

87. Plaintiffs re-allege the foregoing paragraphs as if fully set forth herein.

88. The claims of the '081 patent are invalid for failing to meet the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112 and/or pursuant to common law and/or equitable doctrines. On January 14, 2021, Alvotech USA provided AbbVie Inc. with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B)

describing, on a claim by claim basis, the factual and legal bases of Alvotech USA's opinion that the claims of the '081 patent are invalid. Among other reasons, the claims of the '081 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '081 patent, including, for example, the prior art Alvotech USA produced or otherwise identified to AbbVie Inc. with Alvotech USA's detailed statement. Alvotech USA's detailed statement addressing invalidity of the '081 patent is within AbbVie's possession and is incorporated by reference herein.

89. On March 15, 2021, and pursuant to 42 U.S.C. § 262(*l*)(3)(C), AbbVie Inc. responded to Alvotech USA's detailed statement addressing validity of the '081 patent and purported to provide Alvotech USA with its factual and legal bases for AbbVie Inc.'s opinion that the '081 patent is not invalid. AbbVie filed a suit for infringement of the '081 patent against Alvotech hf. on April 27, 2021 in the Northern District of Illinois, but Alvotech USA, a necessary party, is not subject to personal jurisdiction in that district and venue is improper there under 28 U.S.C. §§ 1400(b) and 1391.

90. As a result of AbbVie's allegations against Plaintiffs, an actual and justiciable controversy exists between Plaintiffs and AbbVie as to whether the claims of the '081 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

91. Plaintiffs are entitled to a judicial declaration that all claims of the '081 patent are invalid. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT III

(Declaratory Judgment of Non-infringement of U.S. Patent No. 9,085,619)

92. Plaintiffs re-allege the foregoing paragraphs as if fully set forth herein.

93. Plaintiffs have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '619 patent under 35 U.S.C. § 271. On January 14, 2021, Alvotech USA provided AbbVie Inc. with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing, on a claim by claim basis, the factual and legal bases for Alvotech USA's opinion that Plaintiffs will not infringe the '619 patent. Alvotech USA's detailed statement is within AbbVie's possession and is incorporated by reference herein. In addition, Plaintiffs cannot be liable for any infringement of the '619 patent because it is invalid and unenforceable.

94. On March 15, 2021, and pursuant to 42 U.S.C. § 262(*l*)(3)(C), AbbVie Inc. purported to provide Alvotech USA with its factual and legal bases for AbbVie Inc.'s opinion that Plaintiffs will infringe the '619 patent. AbbVie filed a suit for infringement of the '619 patent against Alvotech hf. on April 27, 2021 in the Northern District of Illinois, but Alvotech USA, a necessary party, is not subject to personal jurisdiction in that district and venue is improper there under 28 U.S.C. §§ 1400(b) and 1391.

95. As a result of AbbVie's allegations against Plaintiffs, an actual and justiciable controversy exists between Plaintiffs and AbbVie as to the infringement of the '619 patent.

96. Plaintiffs are entitled to a judicial declaration that the making, use, offer for sale, sale, or importation into the United States of Plaintiffs' biosimilar product does not and will not infringe any valid and enforceable claim of the '619 patent under 35 U.S.C. § 271. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT IV

(Declaratory Judgment of Invalidity of U.S. Patent No. 9,085,619)

97. Plaintiffs re-allege the foregoing paragraphs as if fully set forth herein.

98. The claims of the '619 patent are invalid for failing to meet the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112 and/or pursuant to common law and/or equitable doctrines. On January 14, 2021, Alvotech USA provided AbbVie Inc. with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing, on a claim by claim basis, the factual and legal bases of Alvotech USA's opinion that the claims of the '619 patent are invalid. Among other reasons, the claims of the '619 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '619 patent, including, for example, the prior art Alvotech USA produced or otherwise identified to AbbVie Inc. with Alvotech USA's detailed statement. Alvotech USA's detailed statement addressing invalidity of the '619 patent is within AbbVie's possession and is incorporated by reference herein.

99. On March 15, 2021, and pursuant to 42 U.S.C. § 262(*l*)(3)(C), AbbVie Inc. responded to Alvotech USA's detailed statement addressing validity of the '619 patent and purported to provide Alvotech USA with its factual and legal bases for AbbVie Inc.'s opinion that the '619 patent is not invalid. AbbVie filed a suit for infringement of the '619 patent against Alvotech hf. on April 27, 2021 in the Northern District of Illinois, but Alvotech USA, a necessary party, is not subject to personal jurisdiction in that district and venue is improper there under 28 U.S.C. §§ 1400(b) and 1391.

100. As a result of AbbVie's allegations against Plaintiffs, an actual and justiciable controversy exists between Plaintiffs and AbbVie as to whether the claims of the '619 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including

without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

101. Plaintiffs are entitled to a judicial declaration that all claims of the '619 patent are invalid. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT V

(Declaratory Judgment of Non-infringement of U.S. Patent No. 8,926,975)

102. Plaintiffs re-allege the foregoing paragraphs as if fully set forth herein.

103. Plaintiffs have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '975 patent under 35 U.S.C. § 271. On January 14, 2021, Alvotech USA provided AbbVie Inc. with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing, on a claim by claim basis, the factual and legal bases for Alvotech USA's opinion that Plaintiffs will not infringe the '975 patent. Alvotech USA's detailed statement is within AbbVie's possession and is incorporated by reference herein. In addition, Plaintiffs cannot be liable for any infringement of the '975 patent because it is invalid and unenforceable.

104. On March 15, 2021, and pursuant to 42 U.S.C. § 262(*l*)(3)(C), AbbVie Inc. purported to provide Alvotech USA with its factual and legal bases for AbbVie Inc.'s opinion that Plaintiffs will infringe the '975 patent. AbbVie filed a suit for infringement of the '975 patent against Alvotech hf. on April 27, 2021 in the Northern District of Illinois, but Alvotech USA, a necessary party, is not subject to personal jurisdiction in that district and venue is improper there under 28 U.S.C. §§ 1400(b) and 1391.

105. As a result of AbbVie's allegations against Plaintiffs, an actual and justiciable controversy exists between Plaintiffs and AbbVie as to the infringement of the '975 patent.

106. Plaintiffs are entitled to a judicial declaration that the making, use, offer for sale, sale, or importation into the United States of Plaintiffs' biosimilar product does not and will not infringe any valid and enforceable claim of the '975 patent under 35 U.S.C. § 271. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT VI

(Declaratory Judgment of Invalidity of U.S. Patent No. 8,926,975)

107. Plaintiffs re-allege the foregoing paragraphs as if fully set forth herein.

108. The claims of the '975 patent are invalid for failing to meet the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112 and/or pursuant to common law and/or equitable doctrines. On January 14, 2021, Alvotech USA provided AbbVie Inc. with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing, on a claim by claim basis, the factual and legal bases of Alvotech USA's opinion that the claims of the '975 patent are invalid. Among other reasons, the claims of the '975 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '975 patent, including, for example, the prior art Alvotech USA produced or otherwise identified to AbbVie Inc. with Alvotech USA's detailed statement. Alvotech USA's detailed statement addressing invalidity of the '975 patent is within AbbVie's possession and is incorporated by reference herein.

109. On March 15, 2021, and pursuant to 42 U.S.C. § 262(*l*)(3)(C), AbbVie Inc. responded to Alvotech USA's detailed statement addressing validity of the '975 patent and purported to provide Alvotech USA with its factual and legal bases for AbbVie Inc.'s opinion that the '975 patent is not invalid. AbbVie filed a suit for infringement of the '975 patent against Alvotech hf. on April 27, 2021 in the Northern District of Illinois, but Alvotech USA, a necessary

party, is not subject to personal jurisdiction in that district and venue is improper there under 28 U.S.C. §§ 1400(b) and 1391.

110. As a result of AbbVie's allegations against Plaintiffs, an actual and justiciable controversy exists between Plaintiffs and AbbVie as to whether the claims of the '975 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

111. Plaintiffs are entitled to a judicial declaration that all claims of the '975 patent are invalid. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT VII

(Declaratory Judgment of Non-infringement of U.S. Patent No. 8,961,973)

112. Plaintiffs re-allege the foregoing paragraphs as if fully set forth herein.

113. Plaintiffs have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '973 patent under 35 U.S.C. § 271. On January 14, 2021, Alvotech USA provided AbbVie Inc. with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing, on a claim by claim basis, the factual and legal bases for Alvotech USA's opinion that Plaintiffs will not infringe the '973 patent. Alvotech USA's detailed statement is within AbbVie's possession and is incorporated by reference herein. In addition, Plaintiffs cannot be liable for any infringement of the '973 patent because it is invalid and unenforceable.

114. On March 15, 2021, and pursuant to 42 U.S.C. § 262(*l*)(3)(C), AbbVie Inc. purported to provide Alvotech USA with its factual and legal bases for AbbVie Inc.'s opinion that Plaintiffs will infringe the '973 patent. AbbVie filed a suit for infringement of the '973 patent

against Alvotech hf. on April 27, 2021 in the Northern District of Illinois, but Alvotech USA, a necessary party, is not subject to personal jurisdiction in that district and venue is improper there under 28 U.S.C. §§ 1400(b) and 1391.

115. As a result of AbbVie's allegations against Plaintiffs, an actual and justiciable controversy exists between Plaintiffs and AbbVie as to the infringement of the '973 patent.

116. Plaintiffs are entitled to a judicial declaration that the making, use, offer for sale, sale, or importation into the United States of Plaintiffs' biosimilar product does not and will not infringe any valid and enforceable claim of the '973 patent under 35 U.S.C. § 271. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT VIII

(Declaratory Judgment of Invalidity of U.S. Patent No. 8,961,973)

117. Plaintiffs re-allege the foregoing paragraphs as if fully set forth herein.

118. The claims of the '973 patent are invalid for failing to meet the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112 and/or pursuant to common law and/or equitable doctrines. On January 14, 2021, Alvotech USA provided AbbVie Inc. with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing, on a claim by claim basis, the factual and legal bases of Alvotech USA's opinion that the claims of the '973 patent are invalid. Among other reasons, the claims of the '973 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '973 patent, including, for example, the prior art Alvotech USA produced or otherwise identified to AbbVie Inc. with Alvotech USA's detailed statement. Alvotech USA's detailed statement addressing invalidity of the '973 patent is within AbbVie's possession and is incorporated by reference herein.

119. On March 15, 2021, and pursuant to 42 U.S.C. § 262(*l*)(3)(C), AbbVie Inc. responded to Alvotech USA's detailed statement addressing validity of the '973 patent and purported to provide Alvotech USA with its factual and legal bases for AbbVie Inc.'s opinion that the '973 patent is not invalid. AbbVie filed a suit for infringement of the '973 patent against Alvotech hf. on April 27, 2021 in the Northern District of Illinois, but Alvotech USA, a necessary party, is not subject to personal jurisdiction in that district and venue is improper there under 28 U.S.C. §§ 1400(b) and 1391.

120. As a result of AbbVie's allegations against Plaintiffs, an actual and justiciable controversy exists between Plaintiffs and AbbVie as to whether the claims of the '973 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

121. Plaintiffs are entitled to a judicial declaration that all claims of the '973 patent are invalid. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT IX

(Declaratory Judgment of Unenforceability for Inequitable Conduct Regarding U.S. Patent No. 8,961,973)

122. Plaintiffs re-allege the foregoing paragraphs as if fully set forth herein.

123. On January 14, 2021, Alvotech USA provided AbbVie Inc. with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Alvotech USA's opinion that the '973 patent is unenforceable. Alvotech USA's detailed statement addressing unenforceability of the '973 patent is within AbbVie's possession and is incorporated by reference herein.

124. In order to obtain claims on induction dosing regimens, AbbVie argued to the Examiner that a person of skill would be concerned about doses of adalimumab greater than 40 mg/ml. Yet AbbVie knew that its predecessor had run prolonged safety studies that showed adalimumab was safe in doses up to five times greater than the claimed induction doses. Specifically, during the prosecution of U.S. Patent No. 8,889,136 (a parent to the '973 patent), AbbVie Biotechnology Ltd. made the decision to misrepresent the totality of the safety and efficacy data for adalimumab and to not highlight the references that it knew to be of the most significance. On information and belief, AbbVie Biotechnology Ltd. did so with the specific intent to mislead or deceive the Patent Office and with knowledge that the misrepresentations were material to patentability.

125. AbbVie's predecessors sponsored and published the results of clinical trials of adalimumab in rheumatoid arthritis patients (called "DE001/003") that included administration of up to 10 mg/kg adalimumab (approximately 800 mg for a typical 80 kg patient) every other week for up to 2 years. (*See, e.g.*, **Exhibit 6**, Rau 2002 at Table 1 (describing DE001/003 studies); *id.*at ii71-72; **Exhibit 7**, Kempeni 1999 at I71; **Exhibit 8**, Kempeni 2000 at i44, **Exhibit 9**, Rau 2000 at 4; *id.*at Table 1; **Exhibit 10**, den Broeder 2001 at 45-46.) The higher initial doses reported by AbbVie's predecessors are five times larger than the largest doses claimed in the 8,889,136 patent. Rau 2002 reported that "[a]dalimumab was well tolerated in this study. The safety profile of a single doses of adalimumab was comparable to that of placebo." (Exhibit 6, Rau 2002 at ii72.) Kempeni 1999 reported that "the dose increment scheme was followed as planned reaching the maximum dose of 10 mg/kg without any evidence of clinically relevant or dose related adverse effects." (Exhibit 7, Kempeni 1999 at I71; *see also id.* ("After six months, 86% of patients continued to receive treatment with D2E7 indicating that long term intravenous treatment with

D2E7 in the dose range from 0.5 to 10 mg/kg was well tolerated.").) Kempeni 2000 reported that "[i]n the long term open label extensions, a high percentage of patients continued to receive treatment with D2E7 indicating the long term treatment with D2E7 in the dose range from 0.5 to 10 mg/kg was well tolerated." (Exhibit 8, Kempeni 2000 at i44.)

126. AbbVie's predecessors published additional studies demonstrating safety and efficacy of weekly dosing of adalimumab at and above 40 mg. Rau 2002 and Kempeni 2000 describe DE007, in which patients with active RA were given 20 mg, 40 mg, or 80 mg adalimumab weekly or placebo for 12 weeks. (Exhibit 6, Rau 2002 at ii72; Exhibit 8, Kempeni 2000 at i45.) Rau 2002 concludes, "[t]he three doses of adalimumab were similarly well tolerated, the 40 mg and 80 mg doses were equally effective while the 20 mg dose was somewhat less effective." (Exhibit 6, Rau 2002 at ii72.) Additionally, Rau 2002 stated, "DE007 demonstrated that adalimumab treatment produces rapid, sustained responses and is safe and well tolerated, ***with no dose limiting side effects***." (*Id.* (emphasis added); *see also* Exhibit 8, Kempeni 2000 at i45 ("All three doses of D2E7 were efficacious . . . and no dose response relation was apparent at month 3.").)

127. Additionally, AbbVie's predecessors published results from study DE010, in which patients were given 1 mg/kg (equivalent to 80 mg in a typical 80 kg patient) every other week for up to 2 years. (Exhibit 6, Rau 2002 at ii72-73; *see also* Exhibit 8, Kempeni 2000 at Table 1.) The authors of Rau 2002 concluded that "repeated subcutaneous injections of 1 mg/kg adalimumab over a period of two years provides sustained efficacy and is well tolerated . . . ." (*Id*. at ii73.)

128. Kempeni 1999 additionally discussed a clinical trial in which patients received 0.5 mg/kg adalimumab subcutaneously weekly and were up-dosed to 1 mg/kg if initially not responsive. (Exhibit 7, Kempeni 1999 at I71-72.) After three months of treatment, Kempeni 1999

reports, "[w]ith the exception of mild and transient injection site reactions, adverse events occurred with the same frequency and distribution in the D2E7 and placebo groups. The investigators concluded that D2E7 given subcutaneously was safe and as effective as when administered intravenously . . . ." (*Id*. at I72.)

129. Kempeni 2000, which discussed DE001/003, DE007, and DE010, concluded that "[t]reatment with D2E7 has been well tolerated. The rate and severity of adverse events were comparable between all dosage groups of D2E7 and placebo." (Exhibit 8, Kempeni 2000 at i45.)

130. Den Broeder 2001, another reference from a person associated with Abbvie's predecessor looking at the prior studies on adalimumab, concluded that "[s]tudies in more than 1200 patients have demonstrated the efficacy and safety of prolonged administration of this compound either alone or in combination with methotrexate." (Exhibit 10, den Broeder 2001 at 45.)

131. On information and belief, AbbVie Biotechnology Ltd. knew the information regarding all of the safety data was material to the prosecution of AbbVie Biotechnology Ltd.'s claims, including the DE001/003, DE007, and DE010 studies. AbbVie also knew that all of this safety data was in the prior art, including in Rau 2002, Kempeni 1999, Kempeni 2000, Rau 2000, and den Broeder 2001. It also knew that the Examiner had hundreds of references to review and consider. But AbbVie Biotechnology Ltd. made a deliberate decision to misrepresent the totality of the safety and efficacy data for adalimumab and to not highlight the prior art references that it knew to be of the most significance with the intent to deceive the Patent Office. AbbVie Biotechnology Ltd.'s arguments regarding the danger of adalimumab induction doses above 40 mg are directly contradicted by the published prior art studies sponsored by its predecessors demonstrating the safety of adalimumab. This misconduct of misleading the Patent Office

regarding the safety of 160 and 80 mg adalimumab induction dosing tainted numerous patents across the related patent families, including at least the '973 patent.

132. During prosecution of U.S. Patent No. 8,889,136, AbbVie Biotechnology Ltd. through its prosecuting attorneys (including Raymond M. Doss of Ropes & Gray LLP), told the Patent Office that "the increased rates of infections provided the skilled artisan in April 2004 with a motivation to ***not*** use doses of adalimumab greater than 40 mg" (File History of U.S. Patent No. 8,889,136 ("'136 File History"), 3/18/2014 Remarks Made in Amendment at 27 (emphasis in original)), despite publication of the study sponsored by its predecessor demonstrating safety of doses up to 800 mg every other week for up to two years. (*See* Exhibit 6, Rau 2002 at Table 1, ii70, ii72; *see also* Exhibit 9, Rau 2000 at Table 1; *see also* den Broeder 2001 at 45-46.)

133. AbbVie Biotechnology Ltd., through its prosecuting attorneys (including Mr. Doss) and its declarant expert (Dr. Diane Mould), argued to the Patent Office that "the person of ordinary skill would have considered these risks when contemplating a dosing regimen involving simultaneously administering ***four times*** the approved dose of HUMIRA (160 mg) for rheumatoid arthritis followed ***two times*** the approved dose (80 mg) as required by the claimed methods for inducing remission of Crohn's disease." ('136 File History, 3/18/2014 Remarks Made in Amendment at 27 (emphasis in original); *see also* '136 File History, 3/17/2014 Declaration of Dr. Diane Mould at 13 (same).)

134. By focusing on the "approved" dosing for rheumatoid arthritis, AbbVie purposefully misdirected the Patent Office away from its predecessors' publications demonstrating the safety and efficacy of dosing higher than 40 mg every other week. These publications include Rau 2002, Kempeni 1999, Kempeni 2000, Rau 2000, and den Broeder 2001—all of which AbbVie Biotechnology Ltd. knew were in the prior art. As described above, Rau 2002 and Kempeni 2000

reported the safety of repeated adalimumab doses up to and including 800 mg (DE001/003), as well as the safety and efficacy of 40 mg and 80 mg weekly adalimumab doses for 3 months (DE007) and approximately 80 mg every other week dosing for 2 years (DE010). (Exhibit 6, Rau 2002 at Table 1, ii72-73; Exhibit 8, Kempeni 2000 at Table 1.) Kempeni 1999 likewise reported on the safety of repeated adalimumab doses up to and including 800 mg (or 10 mg/kg), as well as 40 mg (0.5 mg/kg) and 80 mg (1 mg/kg) weekly dosing. (Exhibit 7, Kempeni 1999 at I71-72.) With regard to DE007, which reported on ***80 mg weekly*** adalimumab dosing, the authors of Rau 2002 reported that adalimumab "produces rapid, sustained responses and is safe and well tolerated, with no dose limiting side effects." (Exhibit 6, Rau 2002 at ii72; *see also* Exhibit 8, Kempeni 2000 at i45.)

135. AbbVie Biotechnology Ltd. was aware of the safety of prolonged adalimumab dosing above 40 mg at least as early as 2000, as demonstrated in the publication of Kempeni 2000. (Exhibit 8, Kempeni 2000 at i44 ("In the long term open label extensions, a high percentage of patients continued to receive treatment with D2E7 indicating that long term treatment with D2E7 in the dose range from 0.5 to 10 mg/kg was well tolerated."); *see also* Exhibit 6, Rau 2002 at ii72-73; Exhibit 10, den Broeder 2001 at 45 ("Studies in more than 1200 patients have demonstrated the efficacy and safety of prolonged administration of this compound either alone or in combination with methotrexate."); Exhibit 7, Kempeni 1999 at I72 (After three months of 0.5 mg/kg or 1 mg/kg dosing, "[t]he investigators concluded that D2E7 given subcutaneously was safe and as effective as when administered intravenously.").) On information and belief, AbbVie Biotechnology Ltd. knew the information in Rau 2002, Kempeni 1999, Kempeni 2000, Rau 2000, and den Broeder 2001 was material to the prosecution of AbbVie Biotechnology Ltd.'s claims. AbbVie Biotechnology Ltd. made a deliberate decision to misrepresent the totality of the safety

and efficacy data for adalimumab and to not highlight the references that it knew to be of the most significance with the intent to deceive the Patent Office. These material misrepresentations and misleading statements to the Patent Office were directly refuted by credible evidence in Rau 2002, Kempeni 1999, Kempeni 2000, Rau 2000, and den Broeder 2001. This misconduct of not highlighting the references known to be of the most significance and misleading the Patent Office regarding the safety of doses above 40 mg tainted numerous patents across the related patent families, including at least the '973 patent, which is a continuation of the 8,889,136 patent.

136. AbbVie filed a suit for infringement of the '973 patent against Alvotech hf. on April 27, 2021 in the Northern District of Illinois, but Alvotech USA, a necessary party, is not subject to personal jurisdiction in that district and venue is improper there under 28 U.S.C. §§ 1400(b) and 1391.

137. As a result of AbbVie's allegations against Plaintiffs, an actual and justiciable controversy exists between Plaintiffs and AbbVie as to whether the claims of the '973 patent are unenforceable due to AbbVie's inequitable conduct.

138. Plaintiffs are entitled to a judicial declaration that all claims of the '973 patent are unenforceable. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT X

(Declaratory Judgment of Unenforceability Due to AbbVie's Unclean Hands)

139. Plaintiffs re-allege the foregoing paragraphs as if fully set forth herein.

140. Each of the patents-in-suit is unenforceable under the doctrine of unclean hands for at least the reasons set forth in Alvotech USA's January 14, 2021 detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), describing the factual and legal bases for Alvotech USA's opinions

regarding unenforceability. Alvotech USA's detailed statement addressing unenforceability due to unclean hands is within AbbVie's possession and is incorporated by reference herein.

141. AbbVie's "minefield of IP" is a collection of highly-dubious patents, at least 60 of which have been used to threaten every would-be competitor, including Alvotech. While the assertion of one, or five, or ten dubious patents might be readily defeated in court, litigating and defeating 60 or more patents, no matter how weak they all are, is a daunting task—as demonstrated by every prior litigant abandoning the effort. In fact, the overwhelming litigation threatened by AbbVie is truly unprecedented. Data from Docket Navigator reveals no case in U.S. history in which more than 60 patents have been litigated to judgment. Yet AbbVie says that Alvotech must do just that. Defying the statutory scheme, AbbVie refused to pick a subset of patents and, instead, dug its heels in with the position that "if Alvotech wants to resolve *all* issues . . ., it needs to pick *all* patents." AbbVie is thus using its highly-questionable portfolio to "reduce [it's] risk" that even the most frivolous patent will ever face judgment and has "enhance[d] [its] position regarding legal rights that are important to [patent] litigation." *Gilead Scis., Inc. v. Merck & Co.*, 888 F.3d 1231, 1244 (Fed. Cir. 2018). This misconduct constitutes unclean hands, *id.*, and AbbVie's patents are, therefore, unenforceable.

AbbVie's Improperly Inflated Patent Portfolio

142. AbbVie's strategy to subvert the legal process and keep biosimilars off the market began with its patenting scheme to systematically and artificially inflate the size of the Humira® portfolio in the face of efforts by Congress to ease biosimilar entry into the market. BASF AG filed a series of patents on adalimumab (*e.g.*, U.S. Patent No. 6,090,382) and methods of using adalimumab that expired in 2016. When the BPCIA was introduced in 2006, Abbott (AbbVie's predecessor) filed at least thirty-three patent applications over the next five years on adalimumab, extending its patent monopoly beyond the expiration of the original '382 patent. This was a more-

than-five-fold increase over what Abbott had filed in the previous five years, going back to Humira®'s approval. Then, following AbbVie's formation in 2013—at which time Humira® counted for more than 60% of the newly-formed spin-off's revenue—AbbVie filed at least 100 patent applications that have resulted in issued patents with claims relating to adalimumab and/or Humira®, and again, with terms extending beyond the 2016 expiration of the original '382 patent and related patents.

143. AbbVie has achieved this inflated patent portfolio in a number of improper ways, including by patenting purported inventions that AbbVie does not use for Humira®; by seeking multiple patents on the same invention, both as part of the same and different patent families and without informing the PTO of the pending applications in the other families; by seeking patents that cover prior art Humira®; by obtaining patents through inequitable conduct; and by obtaining patents on purported innovations that AbbVie itself did not invent, all of which is detailed in Alvotech's statement under 42 U.S.C. § 262(*l*)(3)(B), describing the bases for Alvotech USA's allegations regarding unenforceability, which are incorporated herein by reference.

144. AbbVie has made no secret of its intent to weaponize its enormous portfolio of patents as a way of scaring off would-be competitors from even daring a challenge to AbbVie's portfolio. In October 2013, AbbVie's CEO, Rick Gonzalez, described AbbVie's patents related to and/or claiming adalimumab (or Humira®) as an "absolute minefield of IP," further stating that "you have to make sure you don't step on any one of them along the way because that's going to create a big problem for you . . . ."

145. Like with any effective minefield, AbbVie has been intentionally secretive about where exactly the mines are located. On June 11, 2014, AbbVie's CFO stated at a Goldman Sachs Healthcare Conference that "we do have a very robust collection of IP," covering "a variety of

different things[,] we're obviously not very specific about what's in there." Thus, AbbVie has intentionally kept potential competitors in the dark about where they can safely step and where they cannot, reducing the likelihood that any competitor would even attempt to chart a safe path to competition.

146. AbbVie publicly touted that the size of its patent portfolio is a way of keeping potential competitors from trying to introduce biosimilar versions of adalimumab. During a Q1 2017 earnings call, AbbVie's CEO stated "our ability to protect Humira . . . was built around a large portfolio of IP, it was never contingent upon any one set of IP or any single set of patents or individual patents." During a Q3 2015 earnings call, AbbVie's CEO stated:

> As you evaluate the timeframe for a potential U.S. biosimilar market entry, it is important that you consider the legal process and the likely timeline for resolution. . . . [T]he total litigation timing may be as long as four or five years. . . . Because of Humira's success, [] damages could be extremely large. . . . [I]n the event a biosimilar attempts to launch at risk, AbbVie will seek injunctive relief.

147. Later, in a Q3 2017 earnings call, AbbVie's CEO stated:

> And so I think what gives us confidence is we firmly believe, one, [an at-risk launch is] an incredibly risky strategy for someone to take based on the size of this asset and the damage that would be done and the consequences of that damage if they lost. Number two, I don't know that I can be any clearer about what our intent is, but I think they understand our intent would be to defend it.

148. AbbVie's CEO's plan of 4-5 years of litigation remains in force, as evidenced by AbbVie's improper filing of its BPCIA patent case in Illinois, which on information and belief, AbbVie perceives as the slower forum as compared to the proper forum of Virginia.

AbbVie's Tactics in Humira®-related BPCIA Pre-Suit Exchanges, Litigations, and Settlement Agreements

149. As the next part of its strategy to keep biosimilars off the market, AbbVie has wielded its inflated portfolio as a weapon—as it had promised to do—and in doing so, has prevented resolution of the merits of AbbVie's portfolio.

150. AbbVie has initiated three previous litigations in the U.S. against Humira® biosimilar BLA applicants: Amgen Inc. ("Amgen"), Sandoz Inc. ("Sandoz"), and Boehringer Ingelheim Pharmaceuticals, Inc. ("BI"). None of these litigations reached a decision on the merits of any patent.

151. During the pre-suit exchanges against BI, AbbVie Inc. threatened infringement on seventy-four patents. (BI's Motion for Leave to File an Amended Answer, Defenses, and Counterclaims from *AbbVie Inc. v. Boehringer Ingelheim International GmbH*, C.A. No. 17-1065-MSG-RL (D. Del. Sep. 21, 2018), ECF No. 209-1.) This bad-faith list included the '382 patent, which had expired, three patents that had been found unpatentable by the PTAB, and sixteen patents for which AbbVie later admitted to BI it lacked any evidence of infringement.

152. AbbVie Inc. made similar baseless threats against both Amgen and Sandoz in BPCIA pre-suit exchanges. (*See, e.g.*, Counterclaims and Answer of Defendants-Counterclaim Plaintiff Amgen Inc. and Amgen Manufacturing Ltd., *AbbVie Inc. et al. v. Amgen Inc. et al.*, C.A. No. 16-666-SLR (D. Del. Sep.13, 2016) at ¶¶ 21-22; Consolidated Class Action Complaint and Jury Trial Demand, *Mayor and City Council of Baltimore v. AbbVie Inc.*, C.A. No. 19-cv-01873 (N.D. Ill. Aug. 9, 2019) at ¶¶ 167-69.) On information and belief, AbbVie Inc. had Amgen's, Sandoz's, and BI's subsection (k) applications from which it could have made a proper infringement assessment before asserting such patents.

153. In addition, when BI raised a defense of unclean hands, AbbVie engaged in improper litigation tactics to delay and prevent even basic discovery, "fight[ing] the 'unclean hands' discovery to the last ditch." (*AbbVie Inc. v. Boehringer Ingelheim International GmbH*, C.A. No. 17-1065-MSG-RL (D. Del. Sep. 21, 2018), ECF No. 410.) The court granted BI's motion to compel relevant discovery from AbbVie related to the unclean hands defense (*id*. at ECF No.

112; *see also id*. at ECF No. 471), and had to further enforce that order when AbbVie failed to comply (*id*. at ECF No. 411). The court warned that AbbVie's continued attempts to block legitimate discovery on unclean hands was "unhelpful, to put it politely," and AbbVie should not "throw more wrenches into the gears" of that allowable discovery. (*Id*. at ECF No. 410.) The court also denied without prejudice both AbbVie's motion to strike the unclean hands defense and its alternative motion for judgment on the pleadings of no unclean hands. (*Id*. at ECF No. 241.)

154. In the pre-suit exchange with AbbVie Inc., Alvotech USA provided its BLA, which identified Alvotech USA's product as a 100 mg/ml formulation. AbbVie responded by identifying 63 patents that it believed Alvotech infringed. Despite having information about Alvotech's formulation, AbbVie included patents and claims directed at 50 mg/ml formulations.

155. Additionally, despite having licensed its patents covering Humira® to at least nine other companies, in the pre-litigation exchange, on March 15, 2021, AbbVie Inc. stated it was not prepared to license any of the 63 patents identified to Alvotech USA. On information and belief, on or about September 28, 2017, AbbVie settled its Humira® biosimilar dispute with Amgen, forcing Amgen to remain off the U.S. market until 2023, but allowing Amgen to launch its biosimilar product in Europe starting in October 2018. On information and belief, AbbVie subsequently settled with at least eight other Humira® (adalimumab) biosimilar manufacturers: Samsung Bioepis, Mylan, Sandoz, Fresenius Kabi, Momenta, Pfizer, Coherus, and BI. On information or belief, AbbVie also has settled or is in the process of settling with adalimumab biosimilar manufacturer Celltrion, again avoiding real challenges to AbbVie's Humira®-related patent portfolio. Other than any settlement with Celltrion, the details of which are unknown, each settlement further delayed potential biosimilar product launch in the U.S. until 2023, ultimately

keeping affordable alternatives from patients in the United States while continuing to extend AbbVie's lucrative monopoly.

156. Prior to their settlements with AbbVie, several companies successfully challenged AbbVie patents covering Humira®. BI and Coherus each challenged AbbVie patents related to the use of adalimumab to treat rheumatoid arthritis in *inter partes* reviews. These IPRs resulted in the invalidation of all claims of three AbbVie Patents directed to 40 mg dosing of adalimumab to treat rheumatoid arthritis: U.S. Patent Nos. 8,889,135; 9,017,680; and 9,073,987. And the Federal Circuit affirmed those decisions in 2020. *See AbbVie Biotechnology, Ltd. v. United States*, 789 Fed. App'x 879, 880 (Fed. Cir. 2020). Sandoz also filed IPRs challenging the claims of additional AbbVie patents, U.S. Patent Nos. 9,090,689 and 9,067,992. The Patent Trial and Appeals Board found Sandoz established a reasonable likelihood that it would prevail in showing that the challenged claims of the two patents are unpatentable. (*See* IPR2017-02105, Paper No. 14 at 34; IPR2017-02106, Paper No. 13 at 37.) These IPRs were terminated after institution as a result of AbbVie's settlement with Sandoz. (*See* IPR2017-02105 and IPR2017-02106, Paper No. 46.)

157. On information and belief, AbbVie has prevented ***any*** company from launching a Humira® biosimilar in the United States until 2023 and has avoided an in-court defense of even a single patent in its "absolute minefield of IP."

AbbVie's 100 mg/ml Formulation

158. In parallel with keeping 50 mg/ml biosimilars off the market in the United States until 2023, AbbVie delayed release to consumers of what AbbVie calls a less painful formulation until such release strategically most benefited AbbVie's overall monopoly.

159. In November 2015, the FDA approved AbbVie's 100 mg/ml citrate-free Humira® formulation. AbbVie has publicly touted this formulation as being less painful than the prior Humira® formulation. In 2015, AbbVie made the 100 mg/ml citrate-free formulation available in

Europe. It was not until 2018 that AbbVie made the 100 mg/ml citrate-free formulation available in the United States. Despite the evident benefit to patients of a less-painful formulation, AbbVie waited nearly three years after FDA approval to launch its higher concentration, reduced injection pain Humira® formulation in the United States.

160. AbbVie's strategic delay in releasing the higher concentration formulation has set AbbVie up to be able to maintain its monopoly even beyond 2023, when the companies with which it has announced settlements are slated to release their biosimilar versions of the 50 mg/ml formulation.

161. On information and belief, by the time AbbVie released its higher concentration formulation in the United States in 2018, AbbVie was banking that other potential biosimilar competitors had committed to developing biosimilars of the pre-existing, lower concentration formulation. The only FDA-approved Humira® (adalimumab) biosimilar drug products (currently scheduled for a 2023 release) are in the first released, lower concentration 50 mg/ml adalimumab formulation rather than the more recently introduced 100 mg/ml formulation.

162. On information and belief, the officers, directors and/or managing agents of AbbVie understand that, under the FDA's current approach, a lower concentration 50 mg/ml adalimumab biosimilar product cannot be substituted for (or deemed biosimilar to) the higher concentration 100 mg/ml Humira® formulation. On information and belief, the higher concentration Humira® formulation accounted for around 70% percent of the United States market for Humira® in 2019 and the higher concentration formulation is expected to account for the vast majority of Humira® sales by 2023. Due to the shift to the higher concentration formulation for

Humira®, the Center for Biosimilars has stated that the biosimilars AbbVie has agreed to let launch in 2023 "Face Product Obsolescence Before Launch."[1]

163. Thus, through its strategic delay in releasing the higher concentration formulation and its settlement with companies set to release the lower concentration formulation in 2023, AbbVie has set itself up to effectively maintain its market monopoly on adalimumab beyond 2023, all to the detriment of patients.

The Enormous Profit to AbbVie from Improperly Extending its Monopoly

164. The reason for AbbVie's improper tactics described above is not a mystery. By managing to extend its monopoly beyond the 2016 expiration of the original adalimumab patents, AbbVie has managed to reap between $10 billion and $20 billion ***per year*** in additional revenues. Due to the nature of Humira®, AbbVie's pricing strategy for Humira®, and AbbVie's above-described tactics, this could continue for years. Between 2003, when the FDA first approved Humira®, and 2016, when the '382 patent expired, AbbVie made nearly $100 billion in revenue, and nearly $50 billion in the United States alone. In 2016, Humira® was AbbVie's largest-selling product (by a factor of 8) and had worldwide net revenues of approximately $16.1 billion. With respect to Humira®, the four highest revenue years for AbbVie have each come after the 2016 expiration of the original adalimumab patents.

165. As such, on information and belief, AbbVie will make more than $40 million ***per day*** from selling Humira® in the United States in 2021 and for each additional year Humira® remains on the market without adalimumab biosimilar competition.

[1] Tony Hagen, *Adalimumab Biosimilars Face Product Obsolescence Before Launch*, THE CENTER FOR BIOSIMILARS (Jan. 6, 2021), https://www.centerforbiosimilars.com/view/adalimumab-biosimilars-face-product-obsolescence-before-launch.

AbbVie's Conduct Constitutes Unclean Hands

166. The doctrine of unclean hands "closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief." *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 814 (1945). Where a patentee's unclean hands have impacted the public, the doctrine "assumes even wider and more significant proportions," because it "not only prevents a wrongdoer from enjoying the fruits of his transgressions but averts an injury to the public." *Id*. at 815. Additionally, "[t]he far-reaching social and economic consequences of a patent . . . gives the public a paramount interest in seeing that . . . such monopolies are kept within their legitimate scope." *Id.* at 816. Proof of fraud is unnecessary; unclean hands may be found where a patent holder's misconduct has "reduced a patentee's risk" or otherwise "enhance[d] the claimant's position regarding legal rights that are important to [patent] litigation." *Gilead Scis., Inc. v. Merck & Co.*, 888 F.3d 1231, 1244 (Fed. Cir. 2018).

167. AbbVie has engaged in a pattern of misconduct designed to build and shield its "patent minefield" from meaningful litigation, thus reducing the risk that those patents would undergo the legal scrutiny necessary to ensure that AbbVie's "monopol[y is] kept within their legitimate scope." *See Precision Instrument*, 324 U.S. at 815. This misconduct has included, at least, artificially inflating the size of its patent portfolio, thus giving AbbVie a substantially larger "minefield of IP" with which to intimidate its competitors into staying off the market. It has included the repeated assertion of expired patents, already-invalidated patents, and patents for which AbbVie lacked any evidence of infringement. It has included shielding even the most frivolous patents from legal scrutiny by letting other would-be competitors launch their products in Europe so long as they agree to drop their challenges to AbbVie's U.S. patents. And it has included inequitable conduct in obtaining many of its Humira®-related patents.

168. AbbVie's misconduct has reduced the risk to AbbVie's Humira®-related patent portfolio both by lowering the likelihood of any company sustaining a challenge to that portfolio and by reducing the resources in terms of time, money, and attention that any challenger could spend on each of AbbVie's patents. AbbVie's complete success to date in staving off any in-court challenges has enhanced its position "regarding legal rights that are important," not just generally, but to this litigation specifically.

169. Although AbbVie has so far included just four patents in its litigation against Alvotech, AbbVie's conduct as it relates to its entire portfolio is still evidence of its unclean hands in this case, for several reasons. First, AbbVie's conduct with respect to that whole portfolio is what has allowed AbbVie to enter this litigation with its large patent portfolio, letting AbbVie Inc. include 63 patents on its 3(A) List (later dropped to 62), and forcing Alvotech USA to provide more than 6,000 pages of responses addressing all 63. Second, AbbVie Inc. has taken the position that the four patents at issue in its Northern District of Illinois complaint and in this complaint will not resolve the question of patent infringement, and that Alvotech USA will still need to overcome the remaining 58 patents on AbbVie Inc.'s 3(C) Statement while refusing to identify with specificity any additional patents. Thus, AbbVie continues to use its entire "minefield of IP" to try to overwhelm Alvotech or intimidate Alvotech, just as it has done with prior companies. Any success AbbVie has on any of the patents currently asserted will have been aided by its prior and future assertion of dozens of other meritless patents. And even when misconduct relates only to a subset of patents, it is appropriate to hold all asserted patents unenforceable where the unclean hands has tainted the other patents. *See, e.g.*, *Gilead Scis.*, 888 F.3d at 1248.

170. In addition to having unclean hands due to the misconduct permeating its portfolio as a whole, AbbVie has unclean hands related to patents asserted in this case, specifically. One

way AbbVie has improperly extended its monopoly beyond 2023 is through the strategically timed introduction of the more recent, higher concentration formulation of Humira®, which AbbVie contends is covered by the '081 and '619 patents at issue in this case.

171. Additionally, as further described above, AbbVie did not actually invent anything claimed in each of the four patents-in-suit. Formulations such as those used in the '081 and '619 patents were developed and publicized by Amgen before AbbVie. The '975 and '973 patents cover methods of using AbbVie's Humira® to treat TNFα-related autoimmune disease—specifically, total ankylosing spondylitis and Crohn's disease. Yet BASF AG disclosed the use of adalimumab to treat TNFα-related autoimmune diseases in its original patent as far back as 1996.

172. Additionally, AbbVie engaged in inequitable conduct as it relates to the '973 patent, as described above, and such inequitable conduct is also relevant to AbbVie's unclean hands.

173. The application of unclean hands here is needed to not only prevent AbbVie from enjoying the fruits of its transgressions, but also to avert an injury to the public. *See Precision Instrument*, 324 U.S. at 815 (holding that where a patentee's unclean hands have impacted the public, the doctrine "assumes even wider and more significant proportions," because it "not only prevents a wrongdoer from enjoying the fruits of his transgressions but averts an injury to the public"). The public has spent more money on Humira® than any drug in U.S. history, leaving little doubt as to the far-reaching socioeconomic consequences of AbbVie's adalimumab monopoly. If AbbVie is not stopped, the public will continue to pay unnecessarily high prices beyond 2023 and as far as 2034—when the last of AbbVie's current patent portfolio (it continues to try and get more) is set to expire—at the cost of $20 billion per year or more.

174. AbbVie filed a suit for infringement of the patents-in-suit against Alvotech hf. on April 27, 2021 in the Northern District of Illinois, but Alvotech USA, a necessary party, is not

subject to personal jurisdiction in that district and venue is improper there under 28 U.S.C. §§ 1400(b) and 1391.

175. In light of the foregoing, there is an actual and justiciable controversy between Plaintiffs and AbbVie concerning whether the claims of the patents-in-suit are unenforceable due to AbbVie's unclean hands.

176. Plaintiffs are entitled to a judicial declaration that all claims of the patents-in-suit are unenforceable due to AbbVie's unclean hands.

COUNT XI

(Declaratory Judgment of Unenforceability Due to Patent Misuse)

177. Plaintiffs re-allege the foregoing paragraphs as if fully set forth herein. In particular, paragraphs 141 to 165 of Count X (Unclean Hands) are equally applicable to AbbVie's patent misuse.

178. Each of the patents-in-suit is unenforceable under the doctrine of patent misuse for at least the reasons set forth in Alvotech USA's January 14, 2021 detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), describing the factual and legal bases for Alvotech USA's opinions regarding unenforceability. Alvotech USA's detailed statement addressing unenforceability due to patent misuse is within AbbVie's possession and is incorporated by reference herein.

179. Patent misuse occurs when a patentee "has impermissibly broadened the 'physical or temporal scope' of the patent grant with anticompetitive effect." *See, e.g.*, *Virginia Panel Corp.*, 133 F.3d 860, 869 (Fed. Cir. 1997). Many kinds of conduct may fall within the scope of patent misuse. One example is where a patentee brings a lawsuit in "bad faith" and with an "improper purpose in bringing the suit." *Glaverbel Societe Anonyme v. Northlake Mktg & Supply Inc.*, 45 F.3d 1550, 1558 (Fed. Cir. 1995). "A purpose is improper if its goal is not to win a favorable judgment, but to harass a competitor and deter others from competition, by engaging the litigation

process itself, regardless of outcome." Additionally, although the "mere accumulation of patents, no matter how many, is not ***in and of itself*** illegal," use of a large portfolio to intimidate competitors "by means of the overpowering threat of disastrous litigation," may be patent misuse. *Automatic Radio Mfg. v. Hazeltine Research*, 339 U.S. 827, 834 (1950) (emphasis added).

180. The facts described above show that AbbVie's scheme is to "engage the litigation process itself"—including the enormous expense and uncertainty of that process—to "deter others from competition," and to avoid legal scrutiny of its patents. AbbVie has used the size of its portfolio to intimidate both Alvotech and prior competitors "by means of the overpowering threat of disastrous litigation." AbbVie's apparent purpose has not been to win a favorable judgment, but rather to avoid any judgment at all by coercing challengers to abandon litigation. AbbVie has pursued those efforts by, among other things, asserting expired patents, invalidated patents, patents obtained through inequitable conduct, and patents for which AbbVie admits to lacking any evidence of infringement. Despite those facially-frivolous assertions, AbbVie has successfully engaged the litigation process itself—including the time and expense of that process—to harass competitors and deter others from competition. To date, AbbVie has settled with every prior competitor, avoiding court scrutiny of its Humira®-related patent portfolio. Thus, AbbVie has impermissibly broadened the physical and temporal scope of its patents, with an anticompetitive effect.

181. Patent misuse may also arise where a patentee enters into a settlement agreement that improperly broadens its patent rights. This can include, for example, a settlement agreement used to improperly "delay[] the entry of competition in the relevant market." *Key Pharms. Inc. v. ESI-Lederle, Inc.*, 1997 WL 560131 (E.D. Pa. 1997). Here, AbbVie has entered into settlement agreements that purport to allow competitors to enter the United States market in 2023. Even if

this were not considered an improper delay, AbbVie structured and timed the settlement agreements to ensure that there will be little, if any, competition even in 2023 and beyond because those products covered by the settlements will have become obsolete before they ever launch. Specifically, the parties with whom AbbVie has settled have announced plans to launch biosimilar versions of the Humira® first released, low-concentration (50 mg/ml) formulation. AbbVie received approval to launch a high-concentration formulation of Humira® in 2015, but did not launch it in the United States until 2018, after the parties with which it settled had committed to the older formulation. By wielding its patent portfolio to enter into settlement agreements that keep those competitors from entering the market until 2023, AbbVie bought itself 4-5 years to shift the market away from the older formulation to the recently released formulation. Thus, AbbVie has ensured that when the low-concentration biosimilars launch in 2023, few doctors will be writing prescriptions for those older generation products. For this reason, the Center for Biosimilars has reported that those products will be obsolete before they ever become available. And through misuse of its patents, AbbVie will be able to maintain its monopolist position.

182. AbbVie filed a suit for infringement of the patents-in-suit against Alvotech hf. on April 27, 2021 in the Northern District of Illinois, but Alvotech USA, a necessary party, is not subject to personal jurisdiction in that district and venue is improper there under 28 U.S.C. §§ 1400(b) and 1391.

183. In light of the foregoing, there is an actual and justiciable controversy between Plaintiffs and AbbVie concerning whether the claims of the patents-in-suit are unenforceable due to AbbVie's patent misuse.

184. Plaintiffs are entitled to a judicial declaration that all claims of the patents-in-suit are unenforceable due to AbbVie's patent misuse.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor against AbbVie Inc. and AbbVie Biotechnology Ltd. and grant the following relief:

A. Declare that Plaintiffs have not, do not, and will not infringe any valid and enforceable claim of the patents-in-suit;

B. Declare that the claims of the patents-in-suit are invalid;

C. Declare that all of the patents-in-suit are unenforceable;

D. Enjoin and restrain Defendants and their officers, agents, servants, employees, attorneys, and those persons in active concert or participation with them from pursuing further charges of infringement or acts of enforcement based on the patents-in-suit against Plaintiffs or their actual and prospective business partners, customers, suppliers, clinical investigators, and anyone in privity with Plaintiffs;

E. Deny Defendants any request for injunctive relief and any other remedy available under Title 35 of the United States Code;

F. Declare that this is an exceptional case in favor of Plaintiffs and award Plaintiffs their reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

G. Award Plaintiffs taxable costs and interest; and

H. Award any and all such relief as the Court determines to be just and proper, including pursuant to 28 U.S.C. § 2202.

JURY DEMAND

Plaintiffs hereby demand a jury trial in this action for any issue so triable.

Respectfully submitted,

Dated: May 11, 2021

By: /s/ *Ahmed J. Davis*

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